OBJECTIVES: Anabolic-Androgenic Steroids (AAS) have been used for muscle mass development for over fifty years. The health outcomes of supraphysiologic doses of AAS have been debated, but most existing information pertains to men. This purpose of the study is to use the National Longitudinal Study of Adolescent Health (AddHealth) to elucidate health outcomes of AAS usage in women. **METHODS:** A cohort study of female AAS users were assessed in two time periods six years apart. Baseline descriptive statistics were used to describe age, income, race, drug use, education, and work performed for the sample. Follow up health outcomes include diabetes, heart disease, hyperlipidemia, anger, physician visit, use of medical care in the last year, Body Mass Index (BMI), blood pressure (BP), C-reactive protein, and HbA1C. Each dependent variable was tested in independent logistic regressions and in sensitivity tests using a MANOVA. **RESULTS:** The sample included 49 female respondents. Education was associated with a two-fold greater odds of AAS use comparing those who attended vocational school to those who attended college (OR=2.22, p=.03). Anger was associated with 88% greater risk of AAS use (OR=1.88, p=.04). HbA1c in the pre-diabetic range, while not statistically significant may be associated with AAS use (OR=1.85, p=.05). No other health outcomes were identified. **CONCLUSIONS:** This study contributes to the literature of female AAS use showing little in health care usage and long term health consequences. Anger is associated with male users but little research exists pertaining to this phenomenon in women. Elevated HbA1c is not commonly associated with AAS use, but due to the small sample size more research should assess AAS use among females.

PIH58

USER AND TREATMENT CHARACTERISTICS OF ORAL CONTRACEPTIVES IN THE EUROPEAN UNION

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OBJECTIVES: As a basis for future safety evaluations of oral contraceptive (OC) use in Europe, current user and treatment characteristics were assessed in four European health care databases. **METHODS:** A descriptive retrospective database study was performed over 2009-2010 in GP databases from The Netherlands (IPCI), UK (THIN) and Italy (HSD) and linked pharmacy dispensing and hospital admission data from The Netherlands (PHARMO). Study follow-up started at the first OC prescription in 2009-2010 (users), one year after database entry or at Jan 1, 2009. Health indicators at start of follow-up included BMI and previous diagnosis of, or use of drugs for selected chronic conditions. Also, previous diagnoses of deep vein thrombosis, pulmonary embolism, cerebrovascular disease, myocardial infarction, breast cancer and cervical cancer were assessed. Treatment characteristics of OC included history of use, type of OC (chemical substance) used during 2009-2010 and switches or discontinuations. **RESULTS:** Among 4.9 million women, 14% had OC prescribed in 2009-2010. In The Netherlands and UK, 12-16% and in Italy 6% had a record of OC use. The prevalence of OC recorded prescription at January 1, 2010 was 81 per 1000 women of all ages and 271 per 1000 women aged 15-24, a much lower figure than what is recorded by surveys, probably due to switches between use and non-use and to reimbursement and/or prescription policies that reduce recording in GP databases. Among the non-users in 2009-2010, up to 22% had a history of OC recorded use. Little differences in health indicators were found between users and non-users in the databases where the information was available. **CONCLUSIONS:** Trends in health among European women in general also apply to OC users. However, OC use is not registered very well in health care databases which limits the possibilities of pharmacovigilance. Distribution channels and reimbursement policies vary, as well as recording in the databases.

PIH59

MEDICATION TREATMENT AND HEALTH CARE UTILIZATION FOR ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) IN GERMANY

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OBJECTIVES: To explore health care utilization and treatment patterns for attention-deficit/hyperactivity disorder (ADHD) in Germany, with particular emphasis on psychostimulant prescriptions. **METHODS:** The complete claims database of the organization of physicians registered with statutory health insurance (SHI) in Nordbaden/Germany was available for analysis, covering the total regional population enrolled in SHI (2.24 million lives). The dataset for years 2003 to 2009 was reorganized as to allow patient-centered evaluation. For calendar year 2009, 21,287 patients with ADHD (male, 15,108; female, 6,179; including 5,931 patients or 27.9% [male, 4,582; female, 1,349] with coexisting conduct disorder [F90.1 or a combination of F90 and F91 codes according to ICD-10]) were available for analysis. **RESULTS:** Preschool children (age 0-5 years) with ADHD were prescribed medication in very rare cases (1.6% in 2009) and after an average lead time of more than one year only. Most received some form of nonpharmacological therapy or were left untreated (42%). In contrast, 41% of children (age group 6-12 years, since 2003, continuously increasing from 32%) and 54% of adolescents (age group 13-17 years, rate remaining stable since 2006) were prescribed either stimulant (methylphenidate, MPH, or amphetamine) or nonstimulant (atomoxetine) drugs. Males and patients with concomitant conduct disorder were more likely to receive medication treatment. Modified-release MPH formulations were more widely used than immediate-release MPH. Overall use of medication increased steadily, from 32.2% of ADHD patients in 2003 to 39.9% in 2009, whereas its rate decreased over time in adult patients (declining from 38% in 2003 to 26% in 2009). – Upon individual review of all prescriptions of ADHD medication for members of the control group, no evidence was found supporting potentially inappropriate use of stimulant medication. **CONCLUSIONS:** Treatment patterns were highly age and gender specific. Except for preschoolers, therapeutic management of patients with ADHD relied heavily on drug treatment.

PIH60

TRENDS IN HOSPITAL ADMISSIONS AMONG MEN AND WOMEN ABOVE THE AGE OF 60 LIVING IN STOCKHOLM AND UPPSALA COUNTIES IN SWEDEN

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OBJECTIVES: To measure the change in the risk of first, second, and third hospitalization and the change in the proportion of hospitalization-free men and women above the age of 60 living in Stockholm and Uppsala counties in Sweden between 1972 and 2010. **METHODS:** Individuals were followed in national registers for hospitalizations and deaths from all causes between 1972 and 2010. Censoring occured at whichever of the following events appeared first; hospitalization (first, second, thrid), death, or December 31, 2010. Survival analysis was used to determine the proportion of hospitalization-free individuals. Discrete time logistic regression was used to obtain the the relative risk (RR) of first, second and third hospitalization. **RESULTS:** An increase in the proportion of hospitalization-free individuals over time was observed for both men and women; for example 87% more 82 year-old men, born in 1928, were free of hospitalizations since the age of 60 compared to those born in 1912. Between the years 1972 and 2010, the average annual decrease in the risk of first hospitalization after the age of 60 was 1% for both men (RR: 0.991, 95%CI: 0.991-0.992) and women. The average annual risk for hospitalization decreased for the second and thrid event as well; however the reduction was not significant. **CONCLUSIONS:** With the increase in the proportion of elderly in the population, the number of individuals with chronic diseases may increase, leading to higher demand for medical and social care. We have observed downward trends of the risk of first, second, and third hospitalization after the age of 60, which could be explained by a postponement of severe morbidity to higher ages. Focus on primary care and changes in inpatient care in Sweden may also partly exaplain the annual reduction in the risk of hospitalization.

PIH62

DO EMA AND FDA HAVE DIFFERENT OPINIONS/REQUIREMENTS IN TERMS OF PEDIATRIC STUDIES FOR SITAGLIPTIN (ALONE OR IN COMBINATION)?

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OBJECTIVES: Since the implementation of Pediatric Regulations/Legislations in the USA (Pediatric Research Equity Act - PREA) and in Europe (Pediatric Investigation Plans - PIPs), product development programs should include pediatric studies. The objective of this study is to review opinions (EMA) and requirements (FDA) given by both agencies in the case of sitagliptin (alone and combined) for the treatment of diabetes mellitus in children. **METHODS:** The EMA and FDA websites were explored to: 1) Identify the products marketed under the INN of sitagliptin (alone or in combination), and 2) Identify the associated PIPs or PREA requirements. The search was performed on January 18, 2013. **RESULTS:** Eight products were marketed in Europe [i.e., sitagliptin (Januvia, Ristaben, Tesavel, Xelvia) and sitagliptin + metformin (Janumet, Efficib, Ristfor, Velmetia)]. Four products were authorized in the USA [i.e., sitagliptin (Januvia); sitagliptin + metformin (Janumet, Janumet XR); sitagliptin + simvastatin (Juvisync)]. The FDA and the EMA provided the same opinion for sitagliptin alone, i.e., deferred pediatric study for patients aged 11 to 16. The FDA and the EMA disagreed on sitagliptin + metformin. The EMA granted a waiver for all subsets of the pediatric population on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments, while the FDA required a pediatric study under PREA for the treatment of type 2 diabetes in pediatric patients aged 11 to 16. As for sitagliptin + simvastatin, the FDA grants a waiver on the grounds that the product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients. **CONCLUSIONS:** The FDA and the EMA have similar opinions except for the combination sitagliptin + metformin. One reason could be the higher prevalence of type 2 diabetes mellitus in children in the USA as compared to Europe.

INFECTION – Clinical Outcomes Studies

PIN1

THE GEOGRAPHIC CORRELATION BETWEEN LYME DISEASE INCIDENCE AND DEGENERATIVE NEUROLOGICAL DISEASE MORTALITY: AN ECOLOGICAL STUDY

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OBJECTIVES: The objective of the present study was to assess the geographic correlation between the incidence of Lyme disease (LD) and mortality due to certain degenerative neurologic diseases (DND) in the US. **METHODS:** For this ecological study, public data sources at the CDC were queried to quantify LD cases and DND deaths for the 5-year period 2002-2006. Alzheimer's disease, Parkinson's disease, and motor neuron disease were preselected as DND of interest. The separate datasets, for LD and DND, were combined by matching county and state names. Counties with at least 1 case of LD and at least 10 deaths due to DND were included in analyses. All analyses were performed in SAS. **RESULTS:** Of the 3141 counties of the US, 1372 reported at least 1 case of LD, 2742 reported at least 10 deaths due to DND, and 1339 met both conditions and were therefore included in analyses. The observed number of LD cases and DND deaths for a single county ranged from 1-6407 (mean: 78; median: 3) and 10-9207 (mean: 165; median: 55), respectively. The Spearman rank test indicated that there is a fair degree of correlation between LD incidence and DND mortality ($r=0.44$, $p<0.0001$). In sensitivity analyses, (1) excluding outliers, defined as observations $\geq 99^{th}$ percentile (LD>53; DND>1255), and (2) evaluating each disease separately, the correlation remained similar in magnitude and statistically significant (coefficient: 0.32-0.41; $p<0.0001$). **CONCLUSIONS:** There is a fair degree of correlation between LD incidence and DND mortality: US counties with a higher number of LD cases tend to have a higher number of